

REMARKS

The specification is amended herein to correct typographical and translation errors. The corrected description is based on the originally filed Japanese PCT application.

Claim 1 is amended by incorporating the subject matter of claim 6. Claims 6, 17 and 20-22 are canceled. Claims 18-19 and 29-31 are withdrawn from consideration.

No new matter is presented.

I. Restriction/Election

The Examiner has withdrawn 18-19 and 29-31 from consideration.

Applicants respectfully request rejoinder of claims directed to methods of making and methods of using the claimed product once the product claims are found allowable in accordance with the provisions of MPEP § 821.04.

II. Response to Claim Rejections Under 35 U.S.C. § 102

In paragraph 4, claims 1-3, 17 and 20-22 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Hasegawa et al (Bull. Chem. Soc. Jpn. 2000, 73, 423-428) or Hisao et al (JP 08-291106).

Without conceding the merits of the rejection, claim 1 is amended herein by incorporating the subject matter of claim 6, which was not included in the rejection. That is, neither of the cited references discloses, teaches or suggests a medicament comprising (2R)-2-propyloctanoic acid or a salt thereof and a basic metal ion wherein the basic metal ion is supplied by at least one selected from a metal salt of phosphoric acid, a metal salt of carbonic acid and a metal salt of sulfurous acid and optionally, a metal hydroxide as recited in amended claim 1.

Thus, present claim 1 and the claims dependent therefrom are not anticipated by either of Hasegawa et al or Hisao et al.

Accordingly, Applicants respectfully request withdrawal of the rejection.

III. Response to Claim Rejections Under 35 U.S.C. § 103

In paragraph 7, claims 1-17, 20-28 and 33-34 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hasegawa or Hisao in view of Ohuchida et al (U.S. Patent No. 6,201,021).

Applicants traverse the rejection.

The medicament of the present invention (claim 1) is either (1) a combination of (2R)-2-propyloctanoic acid with a basic metal ion or (2) a combination of a salt of (2R)-2-propyloctanoic acid with a basic metal ion. These combinations are not described in the references cited. According to these combinations of either (1) a combination of (2R)-2-propyloctanoic acid with a basic metal ion or (2) a combination of a salt of (2R)-2-propyloctanoic acid with a basic metal ion, the medicament of the present invention can be used as an excellent injection precursor, which (1) is resistant to the fluctuation of pH, (2) is not clouded upon formulation of an injection, and (3) does not generate insoluble allotrio, as is described in the present specification (the last paragraph on page 54). These effects can be obtained by buffering function and micelle function which can be achieved by these combinations.

As is pointed out by the Examiner, Ohuchida et al describe a salt of pentanoic acid derivative (sodium salt, potassium salt). However, described in the paragraph bridging pages 2 to 4 of the present specification, when an injection comprising the substance is prepared, there

are critical problems such as that the product cannot be intravenously administered because since a salt, for example, a sodium salt, of (2R)-2-propyloctanoic acid is in a wax form, it is difficult to handle when using the substance as a drug substance for a medicament, and moreover, even if dissolved in water, the substance has a high pH and is susceptible to clouding due to slight fluctuations of the pH.

Accordingly, even if Hasegawa et al or JP 8291106 were combined with Ohuchida et al, the excellent effects of the present invention cannot easily be expected. Thus the present invention is patentable over the cited references, whether taken alone or in combination.

Reconsideration and withdrawal of the rejection is respectfully requested.

IV. Response to Obviousness-Type Double Patenting Rejection

In paragraph 9, claims 1-17, 20-28 and 33-34 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over the claims of U.S. 2007-0066686 (co-pending Application No. 10/574,476).

A Terminal Disclaimer is being submitted herewith, thereby obviating the rejection.

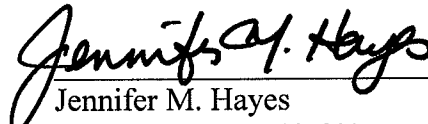
Accordingly, Applicants respectfully request withdrawal of the rejection.

V. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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